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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/745,763 | 12/22/2000 | Kenneth Jacobs | GIN-6046CP | 7028 |
| 5514 | 7590 | 01/28/2004 | EXAMINER | |
| FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | KAM, CHIH MIN | |
| | | | ART UNIT | PAPER NUMBER |

1653

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/745,763 | Applicant(s) JACOBS ET AL. | |
| | Examiner Chih-Min Kam | Art Unit 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 265-267 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 265-267 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. In the preliminary amendment filed December 20, 2000, claims 1-12, 15-36, 38-43, 45-101, 104-116, 118-123, 125-170, 173-205, 208-249 and 252-264 have been canceled. Therefore, claims 13, 14, 37, 44, 102, 103, 117, 124, 171, 172, 206, 207, 250 and 251 are pending and restricted. In the response to restriction requirement filed November 17, 2003, claims 13, 14, 37, 44, 102, 103, 117, 124, 171, 172, 206, 207, 250 and 251 have been cancelled, and new claims 265-267 have been added, thus, claims 265-267 are pending. Applicants do not elect one group, but cancel the remaining claims, and add new claims 265-267, which are directed to the polynucleotide SEQ ID NO:35, the polypeptide SEQ ID NO:36 and related sequences to clone bu45_2. Applicants indicate since SEQ ID NO:36 is the amino acid sequence encoded by SEQ ID NO:35, thus examining all the claims would not add search burden. The response has been considered and the argument is found persuasive, thus claims 265-267 are examined.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because the declaration is not signed by the inventors.

Deposit of Biological Material

3. The Office notes that a deposit of bu45_2 clone, which has been deposited with the American Type Culture Collection (ATCC, 10801 University Boulevard, Manassas, Virginia), has been given the accession number 98369 and deposited under the Budapest Treaty.

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Therefore, no 35 U.S.C. 112 paragraph 1 rejection has been entered even though it is apparent that the claimed deposit material is essential to the claimed invention and the deposit is necessary for an adequate written description and enablement for the claimed invention. Applicant should provide a photocopy of the receipt of the certificate of deposit.

Objection to New Matter Added to Specification

4. The amendment filed November 17, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate a polynucleotide encoding the full-length protein encoded by cDNA insert of clone bu45_2 deposited under accession number "ATCC 98639", however, the new claim (claim 265, part (f)) in the amendment recites the new matters.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 265-267 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a polynucleotide comprising SEQ ID NO:35, specific fragments of SEQ ID NO:35 or the nucleotide sequence of a protein coding sequence of clone bu45_2 deposited under accession number ATCC 98369, a polynucleotide encoding a protein comprising SEQ ID NO:36 or a functional fragment thereof, the allelic variant or a species homolog of the

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polynucleotide, or a polynucleotide that hybridizes under stringent conditions to the polynucleotide (claim 265); a polypeptide comprising SEQ ID NO:36 or a fragment of SEQ ID NO:36, the amino acid sequence encoded by the cDNA insert of clone bu45_2 deposited under accession number ATCC 98369 (claim 266); and a gene corresponding to the cDNA sequence of SEQ ID NO:35 (claim 267). The specification indicates that the invention is related to the novel polynucleotides and the proteins encoded by such polynucleotides (page 5, lines 5-7), and a polynucleotide has been identified as clone "bu45_2", which encodes a secreted or transmembrane protein and the nucleotide sequence of bu45_2 is determined as SEQ ID NO:35 (page 113, lines 2-15). The specification also indicates the nucleotide sequence of bu45_2 was searched against nucleotide sequence databases, which demonstrated at least some similarity with sequences identified as AA041196, AA452391, Q61260, R13864 and R18560; the predicted amino acid sequence for bu45_2 was searched against amino acid databases, which demonstrated at least some similarity to sequences identified as R99416 (aminopeptidase precursor of *Aeromonas caviae*); and based on sequence similarity, bu45_2 proteins and each similar peptide may share at least some activity (page 113, lines 18-32). However, the specification does not disclose the sequence similarity between the identified polynucleotide sequences and SEQ ID NO:35, nor indicates the sequence similarity between the identified polypeptide sequences and bu45_2 proteins. Since the specification has not shown the sequence identities between the bu45_2 protein or polynucleotide with a known protein or polynucleotide, it would be necessary to identify the function or activity of the protein for its use. However, the specification has not identified or demonstrated the specific uses or biological activities of bu45_2 proteins (e.g., SEQ ID NO:36) or the polynucleotides of bu45_2 (e.g., SEQ ID NO:35),

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although it indicates the polypeptides and the proteins of the invention such as SEQ ID NO:35 and SEQ ID NO:36 are expected to exhibit one or more uses or biological activities, which are listed at pages 173-189. Since the direct correlation between the biological activity and the polypeptide is not revealed, and the specific uses of the bu45_2 protein and polynucleotide are not demonstrated, the instant invention does not possess a specific or a well-established utility, although there is a general utility that is applicable to the broad class of proteins or polynucleotides. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, production of antibodies to identify other related proteins or use of polynucleotides to identify other related sequences do not constitute substantial utilities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 265-267 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.
7. Claims 265 and 266 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 265 and 266 are directed to a polynucleotide comprising SEQ ID NO:35, specific fragments of SEQ ID NO:35 or the nucleotide sequence of a protein coding sequence of clone bu45_2 deposited under accession number ATCC 98369 (in part (f) of claim 265, ATCC 98639 being cited), a polynucleotide encoding a protein comprising SEQ ID NO:36 or a functional fragment thereof, the allelic variant or a species homolog of the polynucleotide, or a polynucleotide that hybridizes under stringent conditions to the polynucleotide (claim 265); a polypeptide comprising SEQ ID NO:36 or a fragment of SEQ ID NO:36, the amino acid sequence encoded by the cDNA insert of clone bu45_2 deposited under accession number ATCC 98369 (claim 266). The specification indicates a polynucleotide encoding the full-length protein encoded by cDNA insert of clone bu45_2 deposited under accession number ATCC 98369 (page 19, lines 36-37), it does not indicate the clone is deposited number "ATCC 98639". The specification also indicates the fragments of the proteins are capable of exhibiting biological activity (page 166, lines 8-19), and the fragments can contain a segment preferably 8 or more contiguous amino acids that share at least 75% sequence identity with the such segment of the disclosed protein (page 168, lines 3-14). However, the specification does not specify which fragment of SEQ ID NO:36 is biologically active, what biological activity the fragment has, which fragment of SEQ ID NO: 35 encodes a biologically active fragment of SEQ ID NO:36. There is no disclosure indicating all the fragments of SEQ ID NO:36 containing residues 231-240 are functional, and the specification has not identified any biologically active fragment of SEQ ID NO:36 or any nucleotide sequence encoding the biologically active fragment of SEQ ID

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NO:36. Without guidance for structure to function/activity, one skilled in the art would not know which region or residue(s) of SEQ ID NO:36 is essential for function/activity and how to identify a functional polypeptide. The lack of a structure to function/activity relationship and the lack of representative species for the biologically active fragment of SEQ ID NO:36, and the nucleotide sequences encoding the biologically active fragment of SEQ ID NO:36 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 265 and 266 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claim 265 is indefinite as to “having biological activity” in part (j), it is not clear what biological activity is referred to.
10. Claim 266 is indefinite because of the use of the term “substantially free”. The term “substantially free” renders the claim indefinite, it is not clear what amount of other mammalian proteins is contained in the protein as to “substantially free”, e.g., does the protein contain 0%, 1%, 5% or 10 % other mammalian proteins?

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 265 and 266 are rejected under 35 U.S.C. 102(a) as being anticipated by Jacobs *et al.* (WO 97/39030, October 23, 1997). The priority date for SEQ ID NOs:35 and 36 is March 19, 1998 (application 09/044,466).

Jacobs *et al.* teaches a protein comprising an amino acid sequence of SEQ ID NO:12 (472 amino acids), which has 99.7% sequence identity with SEQ ID NO:36 (see attached sequence match; claim 266, parts (b) and (c)), and a polynucleotide encoding a protein comprising SEQ ID NO:12 (see attached amino acid sequence against nucleotide sequence; page 4, lines 1-2, 5-6, 26; page 10, lines 3-4; page 12, lines 16-34; claims 265, parts (j) and (k)).

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

January 23, 2004



ROBERT A. WAX
PRIMARY EXAMINER